

**REMARKS**

This paper is in response to the final Office Action mailed on April 21, 2005. Because this amendment is submitted with a certificate of mailing in compliance with 37 C.F.R. §1.8 on or before the shortened statutory period for reply set to expire on July 21, 2005, this amendment is timely filed. Moreover, because this application is submitted within two (2) months of the mailing of the above-identified final Office Action, Applicants are entitled to an Advisory Action issued prior to the expiration of the shortened statutory period for reply.<sup>1</sup>

**I. STATUS OF AMENDMENT**

Claims 1, 5 to 14, 17 to 21, 23 to 27, 29, 30 and 32 to 37 are pending in this application with Claims 2 to 4, 15, 16, 22, 28 and 31 having been previously canceled without prejudice. Independent claims 1, 11, 17, 27, 30, and 36 and dependent claims 6 and 14 are amended herein. No new claims have been added. The drawings are objected to under 37 C.F.R. §1.83(a). Applicants submit that no additional claim fees over and above those originally paid are required in connection with this application. However, please charge Deposition Account No. 02-1818 for any insufficiency of payment, excluding the issue fee, during the prosecution of this application.

**II. OBJECTIONS**

The drawings have been objected to for failing to show every feature of the invention specified in the claims. Applicants respectfully traverse this rejection and assert that the subject matter for which protection is sought is so well-understood as to obviate the need for additional drawings and figures. See 35 U.S.C. §113. In particular, Applicants assert that a controller or

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<sup>1</sup> Of course, Applicants acknowledge that should the Advisory Action be issued after the expiration of the three month shortened statutory period, extension fees will be calculated from the mailing date of the Advisory action.

control device, a hemodialysis machine, a cordless interface and electrical connections for a hemodialysis machine are well understood by those skill in the art of needle dislodgement detection and are not required for a complete understanding of the claimed invention. For all of these reasons, applicants submit that the objections to the drawings have been overcome. Withdrawal of this objection is respectfully requested.

The Abstract of the disclosure has been objected to as containing legal phraseology. Thus, the Abstract beginning on page 21, line 1 has been amended to remove the words “capable, comprising, and adapted.” In light of these amendments, Applicants submit that the Abstract is in proper form. No new matter has been added by this amendment. Withdrawal of this objection is respectfully requested.

### III. CLAIM REJECTIONS

The Office Action rejects claim 37 under 35 U.S.C. §112, 2<sup>nd</sup> ¶ as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; Claims 1, 7, 8, 10, 17, 27 and 30 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,078,682 (hereinafter “*Miki*”); Claims 23, 24, 29 and 32 to 37 under 35 U.S.C. §103(a) as being unpatentable over *Miki*, in view of U.S. Patent No. 4,655,742 (hereinafter “*Vantard*”); Claims 5, 6, 9, 11 to 14 and 17 to 21 under 35 U.S.C. §103(a) as unpatentable over *Miki*, in view of WIPO No. WO 99-26686 (hereinafter “*Goodman*”); and Claims 13, 14, 19, 20 and 21 under 35 U.S.C. §103(a) as over *Miki* and *Goodman* and further in view of U.S. Patent No. 6,445,304 (hereinafter “*Bandeian*”).

As an initial matter, presently presented dependent claims 6 and 14 have been amended to provide clarity and consistency throughout the claims. Moreover, Applicants submit that

these claim amendments merely clarify subject matter originally found in the claims, and in no way limit or narrow the scope of protection sought.

Applicants respectfully traverse the rejection of Claim 37 as indefinite. In particular, Claim 37 has been amended to depend from independent Claim 36. Thus, Applicants submit this claim to be in proper form and not indefinite. Withdrawal of this rejection is requested.

Applicants respectfully traverse the rejections of presently presented claims 1, 7, 8, 10, 17, 27 and 30 as anticipated<sup>2</sup> by *Miki*. Amended independent claims 1, 11, 17, 27, 30 and 36 recite, in relevant part, an apparatus for detecting dislodgement of a needle including a barrier pad capable of absorbing blood lost from the patient due to the dislodgement of the needle and a sensor holder adapted to secure the sensor and the barrier pad adjacent to the needle, wherein the sensor holder secures the barrier pad between the sensor and the needle such that the sensor does not contact blood upon detection thereof. In other words, the barrier pad separates the sensor and the needle inserted into the patient to prevent the sensor from directly contacting blood lost from the patient due to the dislodgement of the needle.

*Miki* does not disclose, or even suggest a sensor holder adapted to secure a barrier pad between the sensor and the needle. *Miki* simply discloses a system for monitoring the pressure within a transfusion apparatus. The pressure measurements can be used, in turn, to monitor the operation of the overall system to prevent overpressures from harming patients. Because *Miki* does not disclose a barrier pad of any kind, much less a sensor holder adapted to secure the

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<sup>2</sup> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See also MPEP § 2131.02. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

barrier pad between the sensor and the needle, *Miki* does not anticipate or render obvious the presently presented claims 1, 7, 8, 10, 17, 27 and 30,

Applicants respectfully traverse the rejections of presently presented claims 5, 6, 8, 11 to 14, 17 to 21, 23, 24, 29 and 32 to 37 as obvious over *Miki* in view of *Vantard*, *Goodman*, and *Bandiean*. None of the relied upon references taken alone or in combination discloses or even suggests providing a barrier pad between the sensor and the needle much less providing a sensor holder adapted to secure the barrier pad between the sensor and the needle such that the sensor does not contact blood. Moreover, none of the cited references even recognizes that by preventing contact between the blood lost due to the dislodgement of the needle and the sensor, the apparatus can be reused without having to clean the sensor. See page 11, lines 12 to 14. As previously discussed, *Miki* simply discloses a system for monitoring the pressure within a transfusion apparatus and does not disclose a barrier pad of any kind, much less a sensor holder that secures the barrier pad between the sensor and the needle.

*Vantard*, *Goodman*, and *Bandiean*, either alone or in combination with *Miki*, or each other, do not supply the disclosure and teachings necessary to establish a *prima facie* case of obviousness<sup>3</sup>. In particular, *Vantard* does not disclose a barrier pad of any kind. *Vantard* simply discloses a blood processing apparatus that includes a semipermeable membrane for filtering blood. Similarly, *Goodman* does not disclose a barrier pad, much less providing a sensor holder

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<sup>3</sup> To establish a *prima facie* case of obviousness, three basic criteria must be met.

(1) First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

(2) Second, there must be a reasonable expectation of success.

(3) Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

to secure a barrier pad between a sensor and a needle. Rather, *Goodman* discloses a medical extravasation device that includes an electrode patch which must be attached directly to the skin for sensing electrical information. In fact, if the electrode patch were to be separated from the skin by a barrier pad, the medical extravasation device of *Goodman* would likely be rendered inoperable for its intended purpose.

*Bandeian* does not disclose a barrier pad much less a sensor holder adapted to secure a barrier pad between the sensor and the needle. *Bandeian* discloses a medical alarm system for detecting excess bleeding. In particular, *Bandeian* discloses a normally open electrical circuit that utilizes electrically conductive blood in direct contact with the circuit elements to close the circuit, i.e., make electrical contact, and sound the alarm. Thus, the system of *Bandeian* teaches away from the claimed device because direct contact with the blood is not only desirable, it is required to make the system operate as intended. By way of contrast, as previously discussed, the claimed barrier pad prevents contact between the sensor and the blood.

Because the cited references do not disclose, or even suggest, providing a barrier pad between the sensor and the needle, the pending claims 1, 5 to 14, 17 to 21, 23 to 27, 29, 30 and 32 to 37 are not anticipated by these references, and the references cannot be the basis of a *prima facie* case of obviousness. Furthermore because none of the reference even recognizes the advantage of utilizing a barrier pad to separate the sensor from the needle in order to allow reuse of the sensor in the event of blood loss from the patient due to the dislodgement of the needle, there would be no suggestion or motivation to modify these references as recited by claims 1, 5 to 14, 17 to 21, 23 to 27, 29, 30 and 32 to 37. Thus, the pending claims are patentable over any combination of *Miki*, *Vantard*, *Goodman*, and *Bandiean*.

**IV. CONCLUSION**

For the foregoing reasons, Applicants respectfully submit that the present application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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